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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,170	01/19/2001	Troy J. Chapman	353532000610	1930
7590 11/01/2005 PHILIP S. JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER DAVIS, DANIEL J	
			ART UNIT 3733	PAPER NUMBER

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/766,170	CHAPMAN, TROY J.	
	Examiner	Art Unit	
	D. Jacob Davis	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 and 31-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 20-22 and 31-38 is/are rejected.
- 7) ☒ Claim(s) 18-19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/20/03 7/23/04 7/23/04 3/9/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Once the coupling surrounds the tube as required in the claims, it cannot have “an inner diameter 10 to 30 percent smaller than an inside diameter of the tube.”

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether or not the graft vessel and the suture are positively recited. Examiner assumes for purposes of examination that they are not positively recited.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 12, 13, 16, 17, 31, 34 and 35 and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,723,004 to Dereume et al. Dereume discloses an “anastomosis device” (figure 21) that is capable of end to side anastomosis comprising a graft vessel 24, a coupling member 23, and a flexible tubular member 22. Graft vessels may be artificial or real. The coupling member is compressed and then self-expanded when implanted within a vessel. The device is designed to be placed in a bifurcated vessel system. Such a system comprises three vessels: the aorta and the right and left iliac arteries. The aorta is considered the target vessel. The branches of the device extend outside of the target vessel and into the right and left iliac arteries.

The device further comprises a tubular member 22. The diameter of the tubular member is inherently between about .5 to 6.0 mm since that is approximately the size of a vessel.

With regard the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over the Dereume device which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). *Kalman v. Kimberly Clark Corp.*, 218

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USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Claim 16 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as being unpatentable over Dereume. Dereume discloses the coupling member that inherently has an outer diameter in an expanded state that is between about 10 to 80 percent larger than an inside of the target vessel since the graft must be larger than the vessel walls to maintain its position. In the alternative, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the coupling member at least about 10 percent larger than a vessel wall to prevent graft movement.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dereume. Dereume is silent regarding the biocompatibility of the tubular member 22. Nevertheless, it would have been obvious to one of ordinary skill in the art at the time the

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invention was made the tubular member 22 biocompatible since the device is inserted within the body. Figure 3 illustrates that the tubular member 22 may be a coil 32.

Claims 5 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dereume in view of U.S. Patent No. 5,670,161 to Healy et al. Dereume is silent regarding a plastic flexible tube. The reference discloses element 22 or coil 32 to be spring-loaded. Healy teaches that spring biased stents may be made of a plastic. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the stent out of a plastic material since it is biocompatible and in this case may be spring biased into position.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dereume in view of U.S. Patent No. 5,830,229 to Konya et al. Dereume is silent regarding the material nature of the flexible tube 22 or 32 except that it is spring-biased. Konya discloses in column 2, lines 55-60 that stainless steel may be used as a spring biased material. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the stent out of stainless steel since Konya discloses that the material is biocompatible and may be spring biased into position.

Claims 10, 11, 14 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dereume in view of U.S. Patent No. 5,824,040 to Cox et al. Dereume fails to disclose that the inner and outer layers i.e. the graft vessel 24 and coupling member 23 are made of low durometer silicon or a foam. (It is noted that the inner and outer layers are not positively recited in the claims.) Cox teaches in column 15, lines 1-22 that a graft made of low durometer silicon

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or foam silicon. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the Dereume inner and outer layers out of a low durometer silicon or a foam silicon material in order to providing strength to the graft.

Claims 20-22, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dereume in view of U.S. Patent No. 6,447,540 to Fontaine et al. Dereume is silent with respect to a sheath or introducer to assist in graft advancement. Fontaine teaches a sheath having a groove 50. "Stents [are] contained by a removable sheath so as to facilitate [their] introduction into a blood vessel or other body portion" (column 1, lines 52-54). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the removable sheath (introducer) taught by Fontaine to the Dereume stent device to facilitate its introduction into a blood vessel.

Allowable Subject Matter

Claims 18 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The only IDS filed in October of 2003 is dated October 20, 2003. That IDS is included in this action.

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Response to Arguments

Applicant's arguments filed August 8, 2005 have been fully considered but they are not persuasive. The Dereume et al. device is fully capable of being used as described by the functional limitations of the claims.

Applicant's arguments regarding the Suyker et al. reference (WO 99/21491) is persuasive and the rejections are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Jacob Davis whose telephone number is (571) 272-4693. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DJD


EDUARDO C. ROBERT
PRIMARY EXAMINER